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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/480,908      | 06/07/1995  | GARY K. MICHELSON    | P-12552             | 9745             |

22882 7590 09/19/2006

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| EXAMINER |
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BROWN, MICHAEL A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3764

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                    |  |
|------------------------------|-------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>08/480,908 | Applicant(s)<br>MICHELSON, GARY K. |  |
|                              | Examiner<br>Michael Brown     | Art Unit<br>3764                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-25, 28-156, 158-162, 164-168, 170-174, 176-180 and 182-192 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-25, 28-156, 158-162, 164-168, 170-174, 176-180 and 182-192 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-20-00</u>   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Note: This office action wasn't made a final because the attorney indicated that McKay, which was used in the last office action is an improper reference.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 11-25, 28-31, 33-75, 77-153, 158-159, 164-165, 170-171, 176-177, and 182-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godefroy in view of Kulich (5,458,638).

Godefroy discloses in figures 1-9 an interbody spinal implant comprising a body (the body in fig. 1), having an insertion end 3, a trailing end (at 22), including a thread (13, 14), the body is substantially frusto-conical shaped (fig. 1), the body is substantially cylindrical shaped (fig. 1), the leading end 3 is larger than the trailing end (fig. 1), the implant includes a bone ingrowth material, fusion promoting material 100, the body has openings (9, 10), the thread radius is variable (because of the shape of the body), the body is a porous material (having openings), an internal chamber (the inside of the body), a wall 2 surrounding the inner chamber, the wall has openings ((9, 10), an engagement means (col. 3, lines 45-47), at least one truncated side 6, that forms a planar surface (fig. 4), the body has an upper portion (fig. 1) and a lower portion (fig. 1), a second truncated side 5, the body is made of a material stronger than bone (metal).

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Godefroy discloses an implant comprising a pair of arcuate surfaces (the surfaces of 2 and 4) and a pair of planar surface (the surfaces of (5, 6)). However, it could be argued that Godefroy doesn't disclose threads on the body, a means for closing the body, the body having wells having partial walls, a thread being on the truncated wall. Kuschlich teaches in figures 2a a tapered spinal implant comprising threads (26, 28) along truncated walls (fig. 2), a means (18, 20) for closing the implant and the body having wells (the wells are formed between the threads). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the spinal implant disclosed by Godefroy could be fabricated with threads along the truncated side walls, means for closing body, wells on the body and threads along the entire walls of the truncated implant. The threads on the truncated planar walls would assist in holding the device in place. The means for closing the body would prevent bone chips or bone grafts from coming out of the implant. The wells would allow bone to grow around the implant. The thread on the outside of the body could be constant or vary. The length, diameter, the insertion end and the trailing end could be within the ranges recited in the claims, because these dimensions are not critical. As for claim 183, Kuschlich teaches a continuous thread extending along a majority of the length. As for claim 186, Godefroy discloses a pair of flat sides (5, 6) that are uninterrupted by the threads .

Claims 8, 32, 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Ray (4,904,260).

Ray teaches in figures 1 a spinal implant that can be made of a bioabsorbable material (col. 5, lines 54-58). It would have been obvious to one having ordinary skill in the art at

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the time that the invention was made that the implant disclosed by Godefroy and taught by Kuslich could be fabricated of a bioabsorbable material as taught by Ray in order to allow the implant to absorb into the body after the healing process is completed.

Claims 154-156, 160-162, 166-168, 172-174, 178-180 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Nies, along with Brekke.

Nies teaches a spinal procedure comprising bone promoting substances that include hydroxyapatite (col. 4, lines 10-15 or hydroxyapatite tricalcium phosphate (col. 3, lines 65-67). Brekke teaches using bone morphogenetic protein to enhance bone growth. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the bone promoting substances as taught by Nies and Brekke could be substituted for the bone promoting substances disclosed by Godefroy and taught by Kuslich because either substance could be used to create fusion between the spinal implant and the vertebrae.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown  
September 15, 2006

A handwritten signature in black ink, appearing to read "Michael A. Brown". The signature is fluid and cursive, with a long horizontal stroke at the end.

**MICHAEL A. BROWN**  
**PRIMARY EXAMINER**